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EXAMINER

PASS, NATALIE

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/881,479 | Applicant(s) ADAMS ET AL. | |
| | Examiner Natalie A. Pass | Art Unit 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>19 December 2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 14 June 2001. Claims 1-47 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claim 10 recites the limitation "the logistics system" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claim 45 is rejected under 35 U.S.C. 102(b) as being anticipated by Sloane, U.S. Patent Number 5, 619, 991.

(A) Claim 45 differs from claim 25 in that it is a World-Wide Web-based portal interface to a system for delivering a medical test to a patient and distributing the results of the test to a physician rather than a method for delivering a test unit to a patient and distributing results of the test.

As per claim 45, Sloane teaches a World-Wide Web-based portal interface to a system for delivering a medical test to a patient and distributing the results of the test to a physician (Sloane; Figure 1, column 2, line 62 to column 3, line 28), comprising:

a secure test ordering interface (Sloane; column 1, line 62 to column 2, line 8, column 2, line 62 to column 3, line 28); and

a secure test result retrieval interface (Sloane; column 1, line 62 to column 2, line 8, column 2, line 62 to column 3, line 28).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1, 3-44, 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane, U.S. Patent Number 5, 619, 991 in view of McMenimen et al., U.S. Patent Application Publication Number 2002/0077850.

(A) As per claim 25, Sloane teaches a method for delivering a test unit to a patient and distributing results of the test, comprising:

(a) receiving an order from a physician for distribution of a test to a patient via a computer coupled to a network (Sloane; column 1, line 62 to column 2, line 8);

(b) verifying the authorization of the physician to place the order (Sloane; column 1, lines 60-61) and the patient to receive the order (Sloane; column 3, lines 54-55);

(e) retrieving test results from the unit (Sloane; column 8, lines 47-56); and

(f) distributing the test results (Sloane; column 1, line 62 to column 2, line 8).

Sloan fails to explicitly disclose

(c) storing tracking information regarding a test unit shipped to the patient; and

(d) shipping the test unit to the patient;

However, the above features are well-known in the art, as evidenced by McMenimen.

In particular, McMenimen teaches

(c) monitoring the "status of shipping and scheduled delivery" (reads on "storing tracking information regarding a test unit shipped") to the patient (McMenimen; paragraph [0027]); and

(d) shipping the test unit to the patient (McMenimen; paragraph [0028]);

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sloane to include these limitations, as taught by McMenimen,

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with the motivations of providing “a system that has the following goals: build customized products to refill the medical institution's inventory order, automatic replenishment of stock in days, and the tracking of manufacturing and product information in order to effectively service customers” (McMenimen; paragraph [0023]).

(B) As per claims 26-28, Sloane and McMenimen teach a method as analyzed and discussed in claim 25 above

wherein said step (a) includes receiving an order via a telephone (Sloane; column 1, line 62 to column 2, line 8, column 5, lines 8-9);

wherein said step (a) includes receiving an order via a secure World Wide Web interface (Sloane; column 1, line 62 to column 2, line 8, column 2, line 62 to column 3, line 14); and

wherein said step (a) includes receiving an order via a facsimile (Sloane; column 1, line 48 to column 2, line 8); Examiner interprets Sloane's teachings of “the use of electronic data communications between the physician and one or more entities which can contribute to the patient's diagnosis and/or treatment” (Sloane; column 1, lines 48-51) to include transmission via a facsimile, and therefore as reading on this limitation.

(C) As per claims 29-35, Sloane and McMenimen teach a method as analyzed and discussed in claim 25 above

wherein said step (c) comprises providing a database including a “serial number” (reads on “test unit identification number” and patient information (McMenimen; paragraph [0050]), and matching (reads on “correlating”) the test unit information number and patient information during shipment and retrieval (McMenimen; paragraph [0050]);

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wherein said step (c) further includes storing, in said database, shipping information including a transmittal date to said patient (McMenimen; Abstract, paragraphs [0027]-[0028], [0049]);

further including a step, following said step (d), of retrieving the test unit from the patient (McMenimen; paragraph [0018], lines 15-16);

further including a step, following said step (e), of retrieving “a ‘used’ device” (reads on “the test unit” from the patient (McMenimen; paragraph [0018], lines 15-16, paragraph [0027], lines 3-4);

wherein said step (f) comprises: (f1) determining a user authorized to receive the test results (Sloane; column 1, lines 60-61, column 3, lines 54-55) and transmitting the test results to the authorized user (Sloane; column 1, line 62 to column 2, line 8);

wherein said step (f) comprises transmitting the test results via a secure World Wide Web connection (Sloane; Figure 1, column 1, line 62 to column 2, line 8, column 2, line 62 to column 3, line 14); and

wherein said step (f) comprises transmitting the test results by facsimile to an authorized recipient (Sloane; column 1, line 48 to column 2, line 8); Examiner interprets Sloane’s teachings of “the use of electronic data communications between the physician and one or more entities which can contribute to the patient's diagnosis and/or treatment” (Sloane; column 1, lines 48-51) to include transmission via a facsimile, and therefore as reading on this limitation.

The motivations for combining the respective teachings of Sloane and McMenimen are as given in the rejection of claim 25 above, and incorporated herein.

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(D) Claim 1 differs from claim 25 in that it is a system for delivering an in-home test device to a patient rather than a method for delivering a test unit to a patient.

System claims 1, 3, 6 repeat the subject matter of claims 25, 27, 25 respectively, as a set of elements rather than a series of steps. As the underlying processes of claims 25 and 27 have been shown to be fully disclosed by the collective teachings of Sloane and McMenimen in the above rejection of claims 25 and 27, it is readily apparent that the system disclosed collectively by Sloane and McMenimen includes the apparatus to perform these functions. As such, these limitations are rejected for the same reasons given above for method claims 25 and 27, and incorporated herein.

(E) As per claims 4-5, 7-11, Sloane and McMenimen teach a system as analyzed and discussed in claim 1 above

wherein the shipping system comprises an interface to a commercial courier service (McMenimen; paragraph [0027]);

wherein the verification system is housed remotely (reads on “at a physically different location from the user interface” (Sloane; Figure 1, column 1, lines 60-61, column 3, lines 54-55);

wherein the verification system includes an authorization routine interfacing with the database (Sloane; Figure 1, column 1, lines 60-61, column 3, lines 54-55); and

wherein the verification system includes a user security hierarchy (Sloane; Figure 1, column 1, lines 60-61, column 3, lines 54-55); Examiner notes that the use of a user security hierarchy for ensuring the protection of data so that data stored in a computer cannot be read or compromised by any individuals without authorization and that provides selected users with

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selective access to particular data was well known in the art at the time the invention was made and Examiner interprets the physician's logging in to the remote computer system (Sloane; column 1, lines 60-61) and the system's prompting for a patient ID number (Sloane; column 3, lines 54-55) as reading on this limitation;

wherein the shipping and device retrieval system includes an interface to the database transferring shipping information to the database (McMenimen; paragraph [0027]);

further including a device return verification application, communicating with the logistics system (McMenimen; paragraph [0027]); and

further including "an updated epidemiological transaction record" (reads on "a data report") generator (Sloane; column 6, lines 13-16).

The motivations for combining the respective teachings of Sloane and McMenimen are as given in the rejection of claim 25 above, and incorporated herein.

(F) Claim 12 differs from claim 1 in that it is a system for delivering a home test unit to a patient rather than a system for delivering an in-home test device to a patient.

System claims 12, 13, 15, 17 repeat the subject matter of claims 1, 2, 6, and 8 respectively. As the underlying elements of claims 1, 2, 6, 8 have been shown to be fully disclosed by the collective teachings of Sloane and McMenimen in the above rejection of claims 1, 2, 6, 8, it is readily apparent that the system disclosed collectively by Sloane and McMenimen includes the apparatus to perform these functions. As such, these limitations are rejected for the same reasons given above for claims 1, 2, 6, 8, and incorporated herein.

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(G) As per claims 14, 16, 18, 19, Sloane and McMenimen teach a system as analyzed and discussed in claim 12 above

wherein the data management system includes at least one database containing patient and physician records (Sloane; Figure 4, column 6, lines 51-53);

further including at least a second database separate from the first database containing a subset of records of said at least one database, and “maintained within a computer located at another one of the entities” (reads on “physically housed at a common courier service”) (Sloane; Figure 1, Figure 6, column 2, lines 54-56, column 3, lines 33-37); Examiner interprets Sloane’s teachings of “each of the entities depicted in FIG. 1 is representative of many similar such entities ... [...] ... dispersed throughout a community or, indeed, the country or the world” as teaching this limitation;

wherein the user levels include members and non-members (Sloane; column 3, lines 53-55);

wherein the user levels include patient members (Sloane; column 3, lines 53-55), patient non-members (Sloane; column 3, lines 55-56), consumer members (Sloane; column 3, lines 9-14), physician members (Sloane; column 3, lines 9-14), and physician non-members (Sloane; column 3, lines 1-28).

(H) As per claims 20-24, Sloane and McMenimen teach a method as analyzed and discussed in claims 12 and 14 above

wherein the test distribution and retrieval system includes use of a common courier (McMenimen; paragraph [0027]);

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wherein the system includes an interface application between the at least one database and the common courier service (McMenimen; paragraph [0027], paragraph [0050]);

wherein each test unit includes “serial number” (reads on “a unique identification code”) which is exchanged between the courier service and the interface application (McMenimen; paragraphs [0027], [0028], [0050]);

wherein said test data distribution system includes a result retrieval system coupled to the test device when the test unit is with the patient (Sloane; column 8, lines 47-56); and

wherein said test data distribution system includes a result retrieval system coupled to the test device when the test device is returned to the distribution and retrieval system (Sloane; column 8, lines 47-64), (McMenimen; paragraph [0027]).

The motivations for combining the respective teachings of Sloane and McMenimen are as given in the rejection of claim 25 above, and incorporated herein.

(I) Claim 36 differs from claim 25 in that it is a system for delivering a medical test to a patient and distributing the results of the test to a physician rather than a method for delivering a test unit to a patient and distributing results of the test.

As per claim 36, Sloane and McMenimen teach a system for delivering a medical test to a patient and distributing the results of the test to a physician (Sloane; column 1, line 62 to column 2, line 8), comprising:

a World-Wide Web based portal including a secure test ordering interface (Sloane; column 2, line 62 to column 3, line 28);

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a database order processing system coupled to the portal (Sloane; Figure 1, Figure 3, Figure 4, column 2, line 62 to column 3, line 28);

a logistics system interface (McMenimen; paragraph [0027]); and

a result distribution system (Sloane; column 1, line 62 to column 2, line 8).

The motivations for combining the respective teachings of Sloane and McMenimen are as given in the rejection of claim 25 above, and incorporated herein.

(J) As per claims 37-44, Sloane and McMenimen teach a system as analyzed and discussed in claim 36 above

wherein said order processing system includes a database including physician, patient, test and device records (Sloane; Figure 1, column 2, lines 49-57, column 6, line 51 to column 7, line 65);

including a database record creation application adding said records to said database (Sloane; column 7, lines 40-65);

wherein said logistics system interface includes a shipping demand order output (McMenimen; paragraphs [0027]- [0028]) ;

wherein said logistics system interface includes a receipt application input accepting shipping numbers, device ID number, and a test identifier number. (McMenimen; paragraphs [0027]- [0028], [0050]);

further including a receiving and testing system accepting returned test units (Sloane; column 8, lines 47-64), (McMenimen; paragraph [0027]);

wherein said receiving and testing system includes a refurbishing facility (McMenimen; paragraphs [0024], [0027]);

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wherein said result distribution system includes a verification sub-system to determine authorized recipients for test results (Sloane; column 1, lines 60-61, column 3, lines 54-55); and

wherein the result distribution system includes “an updated epidemiological transaction record” (reads on “a report”) generator (Sloane; column 6, lines 13-16).

The motivations for combining the respective teachings of Sloane and McMenimen are as given in the rejection of claim 25 above, and incorporated herein.

(K) As per claim 46, Sloane teaches a system as analyzed and discussed in claim 45 above

wherein the secure test ordering interface is coupled to a system for delivering a medical test to a patient (Sloane; column 1, line 62 to column 2, line 8); a verification system coupled to the secure test ordering interface (Sloane; column 1, lines 60-61, column 3, lines 54-55); a retrieval system (Sloane; column 8, lines 47-56); and a verification system (Sloane; column 1, lines 60-61, column 3, lines 54-55).

Sloan fails to explicitly disclose

a system including a shipping system coupled to the secure test ordering interface.

However, the above features are well-known in the art, as evidenced by McMenimen.

In particular, McMenimen teaches

a system including a shipping system coupled to the secure test ordering interface (McMenimen; paragraph [0027]-[0028]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sloane to include these limitations, as taught by McMenimen,

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with the motivations of providing a system with "... a very quick turnaround time, e.g., a total of two days ...[until]... delivery of the product..." (McMenimen; paragraph [0026]).

(L) As per claim 47, Sloane and McMenimen teach a system as analyzed and discussed in claim 46 above

wherein said secure test result retrieval interface is coupled to a result delivery system (Sloane; column 2, line 62 to column 3, line 28), which includes an authorization application (Sloane; column 1, lines 60-61, column 3, lines 54-55) and a patient and physician database (Sloane; Figure 4, column 6, lines 51-53).

8. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sloane, U.S. Patent Number 5, 619, 991 in view of McMenimen et al., U.S. Patent Application Publication Number 2002/0077850 as applied to claim 1 above, and further in view of Welner, U.S. Patent Number 5, 612, 870.

(A) As per claim 2, Sloane and McMenimen teach a system as analyzed and discussed in claim 1 above.

Sloane and McMenimen fail to explicitly disclose a system wherein the test ordering system comprises a call center.

However, the above features are well-known in the art, as evidenced by Welner.

In particular, Welner teaches a system wherein the test ordering system comprises a call center (Welner; column 1, lines 39-40, column 3 lines 21-22).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Sloane to include these limitations, as taught by Welner, with the motivations of providing "a medical ... [...] ...tracking system which facilitates the collection and transmission of test status and result information to the individuals being tested while, at the same time, maintaining the anonymity of such individuals" (Welner; column 1, lines 55-59).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied references, Sparks, U.S. Patent Application Number 2001/0037215, Case, U.S. Patent Application Number 2001/0039502, Rappaport, U.S. Patent Application Number 2002/0007285, Kippenhan et al., U.S. Patent Number 6, 485, 979, Case, U.S. Patent Application Number 2002/0026331, Gottlieb, et al., U.S. Patent Application Number 2002/0007290, Causey, III et al., U.S. Patent Number 6, 558, 320, teach the environment of delivering tests and test results.

10. Any response to this action should be mailed to:

**Commissioner of Patents and Trademarks
Washington D.C. 20231**

or faxed to: **(571) 273-8300.**

For informal or draft communications, please label "PROPOSED" or "DRAFT" on the front page of the communication and do NOT sign the communication. After Final communications should be labeled "Box AF."

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

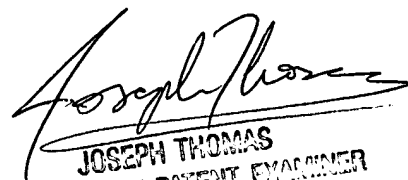
12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (571) 272-3600.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Natalie A. Pass

October 24, 2005



JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER